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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,432	03/03/2004	Thomas Plummer	1OM-P052	2431

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FACTOR & LAKE, LTD
1327 W. WASHINGTON BLVD.
SUITE 5G/H
CHICAGO, IL 60607

EXAMINER	
HELM, CARALYNNE E	
ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/708,432	PLUMMER ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-10,12,13 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 7-10, 12-13, and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 3, 2009 has been entered.

Claim Objections

Claim 1 is objected to because of the following informalities: the recitation of the claimed device includes a living subject as a component implicitly present (see line 17). The living subject is only involved with the device when in use (see preamble). Since this claim is drawn to a device that itself does not include a living subject this recitation is not proper. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 7-10, 12-13, and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 10 recite "a second electrode in direct electrical communication with a living subject's body". This recitation has no basis in the disclosure as filed since no discussion was presented regarding the nature of an electrical communication that may occur between a subject and the claimed device upon its use. Thus this recitation is new matter. Claims 3-5, 7-9, 12-13, and 15-16 are rejected as well since they depend from claims 1 and 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-5, 7, 10, 13, and 16-18 rejected under 35 U.S.C. 103(a) as being unpatentable over Phipps (previously cited) in view of the Table of pKa and PI values for amino acids (previously cited) and Petelenz et al. (US Patent No. 4,752,285).

Phipps teaches an electrotransport device where the pH of the reservoirs is optimized to reduce skin irritation both before and after electrotransport drug delivery (see column 3 lines 60-64). In addition, Phipps teaches that iontophoresis is a widely used process of electrotransport. Phipps generally teaches that these devices have one electrode that is termed a donor or active electrode while the other is the counter or return electrode, serving to close the circuit through the body (see column 1 lines 43-47; instant claim 4). One embodiment of the device is configured where an electrical power source is connected to the donor (active) electrode, which includes the donor reservoir

with the drug to be delivered (see column 5 lines 34-39; instant claims 1, 4, and 17). The invention of Phipps is envisioned using a variety of electrode configurations including one where the power source and electrodes are not a unitary device. In particular, Phipps points to the teachings of Petelenz et al. as one such alternative. Phipps goes on to further describe the donor and counter reservoirs used in the invention. Both are taught as polymeric gel matrices that can include polymers in combination such as Klucel®, a hydroxypropyl cellulose and a viscosity enhancer also exemplified by the instant application, as well as hydroxyethyl cellulose (see column 17 lines 10-13 and 26, and 32-33; instant claims 1, 7, 14, and 17 and instant specification paragraph 17 line 14-16). WATER LOCK®, a sodium polyacrylate polymer, is also taught in this group of suitable polymers and is also taught as a rehydrating agent in the instant specification (see column 17 lines 24-25; instant specification paragraph 17 lines 17-19; instant claim 15). Polymeric buffers are taught by Phipps for use in an anodic reservoir to eliminate competition between the drug to be delivered and the counter ions that can be produced by some buffers (see column 15 lines 7-17). In particular, poly(methylvinyl ether-maleic acid), sold commercially as Gantrez® S95 and S97, is given as a particularly envisioned example of such a polymeric buffer, and is also exemplified in the instant specification (see table 7; instant claim 5 and specification paragraph 15). As the anodic reservoir is taught to be maintained at pH 4 or greater (interpreted as about 4.5), its exemplified buffers are capable of performing this function (see column 15 lines 59-65; instant claims 1, 10, and 16-17). It is also taught that the combination of anionic and cationic buffers can be used where amino acids are

particularly envisioned in either role (see column 14 lines 25-27). Phipps goes on to discuss the classifications of drugs (medicaments) that can be delivered by the invention (see column 18 line 43-column 19 line 45). An example teaches a polyvinyl alcohol based hydrogel that contains lidocaine HCl (medicament) and is used to deliver the drug to a living patient through the skin; here, the potassium concentration is monitored as an indicia of skin irritation and to indicate the need to reposition the device (see example 7). The teachings of Phipps do not explicitly describe the combination of acidic polymeric buffer and a basic amino acid; however, the range over which poly(methylvinyl ether-maleic acid) buffers is nearly the same as that of the acids exemplified. Thus this polymer can be classified as an acidic polymeric buffer. In addition, since both amino acids and polymeric buffers are taught to be available in cationic or anionic form, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine a polymeric buffer with an amino acid buffer.

Phipps refers to figure 6 of Petelenz et al. as a teaching of iontophoretic device configurations that are contemplated within the invention. Figures 5 and 6 depict an electrode assembly where a first electrode is in electrical communication with the medicament in the medicament medium (polymeric matrix) and a second electrode is remote from the first and in contact with the patient's body (see column 13 lines 26-44; instant claims 1, 10, and 17-18). There is no recited requirement that there be any material separating the remote electrode from the subject's skin. Thus, it would have

been obvious to one of ordinary skill that the connection between the electrode and the subject's body would be direct physical, and therefore also electrical, communication.

Glycine (exemplified by applicant's disclosure) is not specifically taught by Phipps as a basic amino acid suitable for use in the invention, however the pKa of its ammonium ion is near that of histidine (see Table of pKa and PI values for amino acids), which is included in the list taught by Phipps. Since the pKa of a compound controls its ability to buffer, the closeness of glycine's value (9.6) to histidine's value (9.17) makes them equivalents for the purposes of the invention of Phipps.

Based upon these teachings, the combination of polymeric buffers with amino acids would have been a known option within the technical grasp of one of ordinary skill in view of the teachings of Phipps. Since both glycine and histidine are included in the twenty most common amino acids, the exchange of one for another for the same purpose would have been obvious to one of ordinary skill (see instant claims 13 and 16). Further, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for the combination of an amino acid with a polymeric buffer as an appropriate buffering system in the invention of Phipps and achieve the instantly claimed invention (anionic polymeric buffer with cationic amino acid). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make and use the invention of Phipps where the polymeric gel matrix includes a polymeric and amino acid buffering system (maintaining the pH at about 4.5), viscosity enhancer, rehydrating agent and medicament with an electrode assembly configured as taught by Petelenz et al. for iontophoretic delivery of the

medicament to a living subject's body. In this configuration the polymeric gel and its associated components would be the medicament medium in contact with electrode 12 as depicted in figure 5 of Petelenz et al. Therefore, claims 1, 4-5, 7, 10, 13, and 16-18 are obvious over Phipps in view of the Table of pKa and PI values for amino acids and Petelenz et al.

Claims 1, 3, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phipps in view of the Table of pKa and PI values for amino acids and Petelenz et al. as applied to claims 1, 4-5, 7, 10, 13, and 16-18 above, and further in view of the lidocaine record in the Merck Index.

The modified Phipps reference makes obvious the recitations of instant claims 1 and 10. Phipps also teaches the incorporation of several classes of drugs (medicaments) that includes anesthetic (see column 18 lines 43-45 and 53-54) In a particular example, Phipps teaches the delivery of the anesthetic lidocaine HCl, a derivative of lidocaine commonly used in the art (see Phipps-example 7 and Lidocaine - Merck Index). As the HCl derivative of lidocaine is commonly used for lidocaine in the pharmaceutical art, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use lidocaine as the medicament in the invention of Phipps. Thus, claims 1, 3, 10, and 12 are obvious over Phipps in view of the Table of pKa and PI values for amino acid, Petelenz et al., and the Merck Index.

Claims 1, 3, 9-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phipps in view of the Table of pKa and PI values for amino acids and

Petelenz et al. as applied to claims 1, 4-5, 7, 10, 13, and 16-18 above, and further in view of Parkinson et al. (previously cited).

The modified Phipps reference makes obvious the recitations of instant claims 1 and 10. Phipps also teaches the incorporation of several classes of drugs (medicaments) that includes anti-inflammatory compounds (see column 18 lines 43-45 and 56). Phipps does not teach the particular type of anti-inflammatory compound or the particular type of active electrode assembly to employ for the donor electrode to use in the invention.

Parkinson et al. teach an iontophoretic device for delivery of anti-inflammatory steroids that includes water-soluble forms of dexamethasone in particular (see paragraph 4 lines 1-21, paragraph 16 and paragraph 17). Parkinson et al. also teach that in an iontophoretic device the active electrode assemblies can be open faced as well as high-density electrodes (see paragraph 16 and paragraph 37 lines 11-13). Since it was know to deliver dexamethasone iontophoretically and the device of Phipps et al. allows this mechanism of delivery with less skin irritation, it would have therefore been obvious to one of ordinary skill in the art to use dexamethasone in the polymeric gel reservoir matrix in the invention of Phipps in view of the Table of pKa and PI values for amino acids and Petelenz et al. It further would have been obvious to select an open faced or high-density electrodes as the active electrode assembly in this invention since these were particular varieties of electrodes known for use in such devices. Therefore claims 1, 3, 9-10, and 12 are obvious over Phipps in view of the Table of pKa and PI values for amino acid, Petelenz et al., and Parkinson et al.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phipps in view of the Table of pKa and PI values for amino acids and Petelenz et al. as applied to claims 1, 4-5, 7, 10, 13, and 16-18 above, and further in view of Hsu et al. (previously cited).

The modified Phipps reference makes obvious the recitations of instant claim 1. Phipps also teaches the incorporation of additional ingredients in the reservoir matrix such as permeability enhancers, but does not teach particular examples of chemicals that could serve in this role. Hsu et al. teach that a variety of compounds are used in the art of drug delivery to enhance skin permeability that includes polysorbate 20 (TWEEN® 20) (see paragraph 5 lines 1-3 and 11). It would have therefore been obvious to one of ordinary skill in the art to use polysorbate 20 as a permeability enhancer in the polymeric gel matrix in the invention of Phipps in view of the Table of pKa and PI values for amino acids and Petelenz et al. Thus claims 1 and 8 are obvious over Phipps in view of the Table of pKa and PI values for amino acids, Petelenz et al., and Hsu et al.

Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phipps in view of the Table of pKa and PI values for amino acids and Petelenz et al. as applied to claims 1, 4-5, 7, 10, 13, and 16-18 above, and further in view of the Grain Processing Corporation WATER LOCK Superabsorbent Polymers reference.

The modified Phipps reference makes obvious the recitations of instant claim 10. In a particular embodiment, Phipps teaches a polyvinyl alcohol (polymer gel matrix) with hydroxypropylmethylcellulose (viscosity enhancer and rehydrating agent) (see column

26 lines 54-58). Phipps also teaches other polymers such as KLUCEL® and WATER LOCK®, that are useful both individually and in combination, as components in the electrode reservoirs (see column 17 lines 10-13 and 26, and 32-33; instant specification paragraph 17 line 14-16). Phipps does not teach a particular variety of WATER LOCK®, but instead implies that any would be suitable. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ WATER LOCK® A220, as a finite number of variants were available and all served the purpose of absorbing water at the time of the invention (see the Grain Processing Corporation WATER LOCK® Superabsorbent Polymers reference). Therefore claims 10 and 15 are obvious over Phipps in view of the Table of pKa and PI values for amino acids, Petelenz et al., and the Grain Processing Corporation WATER LOCK® Superabsorbent Polymers reference.

Response to Arguments

Applicant's arguments filed March 3, 2009 have been fully considered but they are not persuasive.

Applicant's arguments against the rejections made under 35 USC 103(a) are focused on an asserted lack of teaching or suggestion of an iontophoretic device with an active electrode assembly associated with the polymeric gel matrix, where the active electrode assembly includes a first electrode in electrical communication with medicament ions in the polymeric gel matrix as well as a second electrode in direct electrical communication with the living subject's body. As discussed above. Phipps details that in addition to the particular embodiment depicted within the patent, other

configurations of devices are envisioned, in particular those of Petelenz et al. This reference to Petelenz et al. provides teachings of the device configuration of two electrodes where one is in direct electrical contact with the body of a living subject and the other in electrical contact with the medicament ions in the medicament medium (see figure 6). In view of the teachings of Phipps regarding the active electrode reservoir as a polymeric matrix, the medicament medium would be the polymeric matrix with medicament. Therefore Phipps, in view of Petelenz the incorporated reference, does teach the claimed electrode configuration.

Applicant's amendments have obviated the objections and rejection under 35 USC 112, second paragraph in the previous Office action. Therefore these objections and rejections are hereby withdrawn.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-83738373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635